Bone Growth Stimulation

Policy # 00011
Original Effective Date: 05/01/1995
Current Effective Date: 03/15/2017

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member’s contract/certificate, and
- Medical necessity criteria and guidelines are met.

Based on review of available data, the Company may consider noninvasive electrical bone growth stimulation (EBGS) as treatment of fracture nonunion or congenital pseudoarthroses in the appendicular skeleton (the appendicular skeleton includes the bones of the shoulder girdle, upper extremities, pelvis, and lower extremities) to be eligible for coverage.

Patient Selection Criteria for the use of Electrical Bone Growth Stimulation (EBGS) of the Appendicular Skeleton
Coverage eligibility for the use of noninvasive electrical bone growth stimulation (EBGS) of the appendicular skeleton as a treatment of fracture nonunion will be considered when the following criteria are met:

- At least three months have passed since the date of fracture; and
- Serial radiographs have confirmed that no progressive signs of healing have occurred; and
- The patient can be adequately immobilized and is of an age where likely to comply with non-weight bearing.

Based on review of available data, the Company may consider the use of either non-invasive or invasive electrical bone growth stimulation (EBGS) as an adjunct to spinal fusion surgery to be eligible for coverage when patient selection criteria are met.

Patient Selection Criteria for the use of Electrical Bone Growth Stimulation (EBGS) of the Spine
Coverage eligibility for the use of either non-invasive or invasive electrical bone growth stimulation (EBGS) as an adjunct to spinal fusion surgery will be considered when the following criteria are met:

- As an adjunct to spinal fusion surgery for patients with any of the following risk factors for subsequent failed fusion:
  - One or more previous failed spinal fusion(s); or
  - Grade III or worse spondylolisthesis; or
  - Fusion to be performed at more than one level; or
  - Smoking habit; or
  - Diabetes; or
  - Renal disease; or
  - Alcoholism; or
  - Steroid use.
Based on review of available data, the Company may consider noninvasive electrical bone stimulation as a treatment of patients with failed spinal fusion to be **eligible for coverage**. Failed spinal fusion is defined as a spinal fusion that has not healed at a minimum of six months after the original surgery, as evidenced by serial x-rays over a course of three months.

Based on review of available data, the Company may consider low-intensity ultrasound treatment when used as an adjunct to conventional management (i.e., closed reduction and cast immobilization) for the treatment of fresh, closed fractures in skeletally mature individuals to be **eligible for coverage**.

**Patient Selection Criteria for the use of Low-intensity Ultrasound – Fresh Fracture**

Coverage eligibility for low-intensity ultrasound will be considered when candidates for ultrasound (US) treatment are at high risk for delayed fracture healing or nonunion. These risk factors may include either locations of fractures or patient comorbidities and include the following:

Patient comorbidities:
- Diabetes, renal disease or other metabolic diseases where bone healing is likely to be compromised
- Steroid therapy
- Osteoporosis
- History of alcoholism
- History of smoking

Fracture locations:
- Closed radial fractures, posteriorly displaced (Colles’)
- Tibial diaphyseal fractures, closed or Grade I open
- Jones fracture
- Fracture of navicular bone in the wrist (also called the scaphoid)
- Fracture of metatarsal
- Fractures associated with extensive soft tissue or vascular damage

Based on review of available data, the Company may consider low-intensity ultrasound (US) treatment as a treatment of delayed union of bones including delayed union of previously surgically treated fractures, excluding the skull and vertebra to be **eligible for coverage**.

Based on review of available data, the Company may consider low-intensity ultrasound (US) treatment as a treatment of fracture non-unions of bones, including nonunion of previously surgically treated fractures excluding the skull and vertebra to be **eligible for coverage**.

**Patient Selection Criteria for the use of Low-intensity Ultrasound – Non-Union Fracture**

Coverage eligibility for low-intensity ultrasound will be considered when the following criteria are met:
- At least three months have passed since the date of fracture; and
- Serial radiographs have confirmed that no progressive signs of healing have occurred; and
- The patient can be adequately immobilized and is of an age where likely to comply with non-weight bearing.
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When Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on available data, the Company considers the use of invasive or non-invasive electrical bone growth stimulation (EBGS) for other applications including, but not limited to, the treatment fresh fractures, delayed union, immediate postsurgical treatment after appendicular skeletal surgery, stress fractures, arthrodesis or failed arthrodesis, or when patient selection criteria are not met to be investigational.*

(Note: Delayed union is defined as a decelerating fracture healing process, as identified by serial x-rays.)

Based on review of available data, the Company considers implantable and semi-invasive electrical bone growth stimulators for use on the appendicular skeleton to be investigational.*

Based on review of available data, the Company considers semi-invasive electrical bone growth stimulation as an adjunct to lumbar fusion surgery and for failed lumbar fusion to be investigational.*

Based on available data, the Company considers the use of low-intensity ultrasound treatment for other applications including, but not limited to the treatment of congenital pseudarthroses, open fractures, fresh surgically treated closed fractures or stress fractures or when patient selection criteria are not met to be investigational.*

Policy Guidelines
Nonunion
No consensus on the definition of nonunion currently exists. One proposed definition is failure of progression of fracture healing for at least 3 consecutive months (and for at least 6 months following the fracture), accompanied by clinical symptoms of delayed union or nonunion (pain, difficulty bearing weight) (Bhandari, 2012).

The original U.S. Food and Drug Administration (FDA) labeling of fracture nonunions defined them as fractures that had not shown progressive healing after at least 9 months from the original injury. The labeling states: “A nonunion is considered to be established when a minimum of 9 months has elapsed since injury and the fracture site shows no visibly progressive signs of healing for minimum of 3 months.” This timeframe is not based on physiologic principles but was included as part of the research design for FDA approval as a means of ensuring homogeneous populations of patients, many of whom were serving as their own controls. Others have contended that 9 months represents an arbitrary cutoff point that does not reflect the complicated variables that are present in fractures (ie, degree of soft tissue damage, alignment of the bone fragments, vascularity, and quality of the underlying bone stock). Some fractures may show no signs of healing, based on serial radiographs as early as 3 months, while a fracture nonunion may not be diagnosed in others until well after 9 months. The current policy of requiring a 3-month timeframe for lack of progression of healing is consistent with the definition of nonunion as described in the clinical literature.
Delayed Union
Delayed union is defined as a decelerating healing process as determined by serial radiographs, together with a lack of clinical and radiologic evidence of union, bony continuity, or bone reaction at the fracture site for no less than 3 months from the index injury or the most recent intervention. In contrast, nonunion serial radiographs (described above) show no evidence of healing. When lumped together, delayed union and nonunion are sometimes referred to as “ununited fractures.”

Fresh Fracture
A fracture is most commonly defined as “fresh” for 7 days after its occurrence. Most fresh closed fractures heal without complications with the use of standard fracture care (ie, closed reduction, cast immobilization).

Background/Overview
Electrical Bone Growth Stimulation
Both invasive and noninvasive electrical bone growth stimulators have been investigated as an adjunct to spinal fusion surgery, with or without associated instrumentation, to enhance the chances of obtaining a solid spinal fusion. Noninvasive devices have also been investigated to treat a failed fusion. Electrical and electromagnetic fields can be generated and applied to bones through the following methods:

- Surgical implantation of a cathode at the fracture site with the production of direct current electrical stimulation. Invasive devices require surgical implantation of a current generator in an intramuscular or subcutaneous space, while an electrode is implanted within the fragments of bone graft at the fusion site. The implantable device typically remains functional for 6 to 9 months after implantation, and although the current generator is removed in a second surgical procedure when stimulation is completed, the electrode may or may not be removed. Implantable electrodes provide constant stimulation at the nonunion or fracture site but carry increased risks associated with implantable leads.

- Noninvasive electrical bone growth stimulators generate a weak electrical current within the target site using pulsed electromagnetic fields, capacitive coupling, or combined magnetic fields. In capacitive coupling, small skin pads/electrodes are placed on either side of the fusion site and worn for 24 hours per day until healing occurs or up to 9 months. In contrast, pulsed electromagnetic fields are delivered via treatment coils that are placed over the skin and are worn for 6 to 8 hours per day for 3 to 6 months. Combined magnetic fields deliver a time-varying magnetic field by superimposing the time-varying magnetic field onto an additional static magnetic field. This device involves a 30-minute treatment per day for 9 months. Patient compliance may be an issue with externally worn devices.

- Semi-invasive (semi-implantable) stimulators use percutaneous electrodes and an external power supply, obviating the need for a surgical procedure to remove the generator when treatment is finished.

Ultrasound Accelerated Fracture Healing Device
Ultrasound may accelerate healing of fractures by stimulating new bone growth and, therefore, has been proposed as a treatment for fractures with delayed healing or at high risk for nonhealing. Ultrasound treatment can be self-administered with 1 daily 20-minute treatment, continuing until the fracture has healed. The mechanism of action at the cellular level is not precisely known but is thought to be related to a
mechanical effect on cell micromotion/deformation, causing an increase in stimulation of transmembrane cell adhesion molecules and upregulation of cyclooxygenase-2.

**FDA or Other Governmental Regulatory Approval**

**U.S. Food and Drug Administration**

*Electrical Bone Growth Stimulation of the Appendicular Skeleton*

The non-invasive OrthoPak<sup>®</sup> Bone Growth Stimulator (BioElectron) received FDA premarket approval (PMA) in 1984 for treatment of fracture nonunion. Pulsed electromagnetic field systems with FDA premarket approval (all non-invasive devices) include Physio-Stim<sup>®</sup> from Orthofix Inc., first approved in 1986, and OrthoLogic<sup>®</sup> 1000, approved in 1997, both indicated for treatment of established nonunion secondary to trauma, excluding vertebrae and all flat bones, in which the width of the nonunion defect is less than one-half the width of the bone to be treated; and the EBI Bone Healing System<sup>®</sup> from Electrobiology, Inc., which was first approved in 1979 and indicated for nonunions, failed fusions, and congenital pseudarthroses. No distinction was made between long and short bones. FDA has approved labeling changes for electrical bone growth stimulators that remove any timeframe for the diagnosis.

No semi-invasive electrical bone growth stimulator devices with FDA approval or clearance were identified.

*Electrical Stimulation of the Spine as an Adjunct to Spinal Fusion Procedures*

The following implantable device was approved by the FDA through the premarket approval process:

- **The OsteoStim<sup>®</sup>** (Electro-Biology), which may also be marketed under the trade name SPF (Biomet).

The following noninvasive bone growth stimulators were approved by FDA through the premarket approval process:

- In 1999, the SpinalPak<sup>®</sup> bone growth stimulator system (Biolectron, a subsidiary of Electro-Biology, Parsippany, NJ), a capacitive coupling system, was approved by FDA through the premarket approval process for use as an adjunct to primary lumbar spinal fusion at 1 or 2 levels.
- In 1979, the EBI Bone Healing System (Biolectron, a subsidiary of Electro-Biology, Parsippany, NJ), a pulsed electromagnetic field system, was approved by FDA through the premarket approval process for nonunions, failed fusions, and congenital pseudoarthroses. The device is secured with a belt around the waist.
- In 1994, the SpinaLogic Bone Growth Stimulator<sup>®</sup> (Regentek, a division of dj Orthopedics [formerly OrthoLogic, Tempe, AZ]) was approved by FDA through the premarket approval process as a combined magnetic field portable device. This device is secured with a belt around the waist.
- In 1996, the Spinal-Stim Lite<sup>®</sup> (Orthofix, Richardson, TX) was approved by FDA through the premarket approval process as a spinal adjunct to the Physio-Stim. This device was approved to increase the probability of fusion success and as a nonoperative treatment for the salvage of failed spinal fusion, where a minimum of 9 months has elapsed since the last surgery.
- In 2004, the Stim<sup>®</sup> (Orthofix, Richardson, TX), a pulsed electromagnetic field system, was approved by FDA through the premarket approval process as an adjunct to cervical fusion surgery in patients at high risk for nonfusion.
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- No semi-invasive electrical bone growth stimulator devices were identified with FDA approval or clearance.

Ultrasound Accelerated Fracture Healing Device
The Sonic Accelerated Fracture Healing System, SAFHS® (also referred to as Exogen 2000®) was initially cleared for marketing by the U.S. FDA in October 1994 as a treatment of fresh, closed, posteriorly displaced distal radius (Colles) fractures and fresh, closed, or grade I open tibial diaphysis fractures in skeletally mature individuals when these fractures are orthopedically managed by closed reduction and cast immobilization. In February 2000, the labeled indication was expanded to include the treatment of established nonunions, excluding skull and vertebra.

Centers for Medicare and Medicaid Services (CMS)

Electrical Bone Growth Stimulation of the Appendicular Skeleton
Centers for Medicare and Medicaid Services cover noninvasive stimulators for the following indications:
- Nonunion of long bone fractures
- Failed fusion, where a minimum of nine months has elapsed since the last surgery
- Congenital pseudarthroses

Centers for Medicare and Medicaid Services cover invasive stimulators for the following indications:
- Nonunion of long bone fractures

Effective for services performed on or after April 1, 2000, nonunion of long bone fractures, for both noninvasive and invasive devices, is considered to exist only when serial radiographs have confirmed that fracture healing has ceased for three or more months prior to starting treatment with the electrical osteogenic stimulator. Serial radiographs must include a minimum of two sets of radiographs, each including multiple views of the fracture site, separated by a minimum of 90 days.

Electrical Stimulation of the Spine as an Adjunct to Spinal Fusion Procedures
Medicare covers noninvasive electrical stimulators for the following:
- Failed fusion, where a minimum of nine months has elapsed since the last surgery AND
- As an adjunct to spinal fusion surgery for patients at high risk of pseudarthrosis due to previously failed spinal fusion at the same site or for those undergoing multiple level fusion. A multiple level fusion involves three or more vertebrae (e.g., L3-L5, L4-S1, etc.).

Medicare covers invasive electrical stimulators
- As an adjunct to spinal fusion surgery for patients at high risk of pseudarthrosis due to previously failed spinal fusion at the same site or for those undergoing multiple level fusion. A multiple level fusion involves three or more vertebrae (e.g., L3-L5, L4-S1, etc.).

Ultrasound Accelerated Fracture Healing Device
Effective January 1, 2001, ultrasonic osteogenic stimulators are covered as medically reasonable and necessary for the treatment of nonunion fractures. Nonunion fractures of the skull, vertebrae, and those that are tumor-related are excluded from coverage. Ultrasonic osteogenic stimulators may not be used...
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concurrently with other non-invasive osteogenic devices. Ultrasonic osteogenic stimulators for fresh fractures and delayed unions remain noncovered.

**Rationale/Source**
This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. FDA approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, Blue Cross and Blue Shield Association technology assessment program (TEC) and other non-affiliated technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

**Electrical Bone Growth Stimulation of the Appendicular Skeleton**
The evidence for noninvasive electrical bone growth stimulation in individuals who have fracture nonunion includes RCTs and a systematic review. Relevant outcomes are symptoms, change in disease status, and functional outcomes. The FDA approved noninvasive electrical bone growth stimulation for the indications of fracture nonunions and congenital pseudoarthroses in the appendicular skeleton, based largely on studies with patients serving as their own controls. There is also evidence from 2 small sham-controlled RCTs that noninvasive electrical stimulators improve fracture healing for patients with fracture nonunion, although these trials are not high quality. However, there are few nonsurgical options in this population, and the pre-post studies of patients with nonhealing fractures support the efficacy of the treatment. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

The evidence for noninvasive electrical bone growth stimulation in individuals who have delayed fracture union, fresh or stress fracture(s), or who have had surgery of the appendicular skeleton includes RCTs. Relevant outcomes are symptoms, change in disease status, and functional outcomes. Two RCTs found no benefit of electrical bone growth stimulation for fresh fractures. RCTs on delayed union of the other types of fractures were limited by small sample size and did not show a significant difference between study groups. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for implantable and semi-invasive electrical bone growth stimulation in individuals who have any type of fracture, pseudoarthroses, or who have had surgery of the appendicular skeleton includes a small number of case series. Relevant outcomes are symptoms, change in disease status, and functional outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Electrical Stimulation of the Spine**
The evidence for invasive or noninvasive electrical bone growth stimulation in individuals who are at high risk of lumbar spinal fusion failure includes a TEC Assessment and RCTs. Relevant outcomes are symptoms, change in disease status, and functional outcomes. Results from these trials indicate that in patients with risk factors for failed fusion, either invasive or noninvasive electrical bone stimulation increases the fusion rate. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.
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The evidence for noninvasive electrical bone growth stimulation in individuals who are at normal risk for lumbar spinal fusion failure includes RCTs. Relevant outcomes are symptoms, change in disease status, and functional outcomes. Several RCTs have shown increased fusion rates with noninvasive bone stimulation in patient populations that include both high risk and normal risk groups. No studies were identified that studied a population of patients who were all at normal risk for fusion failure. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for noninvasive electrical bone growth stimulation in individuals who have failed lumbar spinal fusion includes a TEC Assessment and studies where patients served as their own controls. Relevant outcomes are symptoms, change in disease status, and functional outcomes. Data indicate that noninvasive electrical stimulation improves the fusion rate in this population. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

Ultrasound Accelerated Fracture Healing Device

For individuals who have fresh closed fractures who receive LIPUS, the evidence includes RCTs and systematic reviews of RCTs. Relevant outcomes are symptoms, morbid events, functional outcomes, and quality of life. This evidence indicates that LIPUS improves clinical and radiographic healing for fresh closed fractures, although the magnitude of benefit may differ depending on the location of the bone and risk factors for healing. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

For individuals who have open fractures or surgically treated closed fractures who receive LIPUS, the evidence includes RCTs. Relevant outcomes are symptoms, morbid events, functional outcomes, and quality of life. Results from RCTs of LIPUS for this patient population are mixed, and do not consistently demonstrate improved outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have fracture nonunion who receive LIPUS, the evidence includes prospective case series. Relevant outcomes are symptoms, morbid events, functional outcomes, and quality of life. The case series are considered adequate evidence for nonunions, due to the negligible chance of healing without intervention and the lack of other noninvasive alternatives. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

For individuals who have delayed fracture union who receive LIPUS, the evidence includes an RCT. Relevant outcomes are symptoms, morbid events, functional outcomes, and quality of life. Evidence for US treatment for delayed fracture union (a moderately sized double-blinded sham-controlled trial) showed a moderate effect size for increased bone mineral density and a trend toward increased rate of clinical healing with US treatment. In addition, improvements in intermediate outcomes (eg, radiographic appearance), combined with the efficacy of US for fresh closed fractures and fracture nonunion, make it very likely that this treatment is also efficacious for delayed union. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

For individuals who have tibial stress fractures, osteotomy sites, or distraction osteogenesis who receive LIPUS, the evidence includes small RCTs and nonrandomized comparative trials. Relevant outcomes are
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Symptoms, morbid events, functional outcomes, and quality of life. One small RCT was identified on US for the treatment of tibial stress fractures. LIPUS did not significantly reduce healing time for these fractures in this double-blind study. One small quasi-randomized study was identified on use of US for osteotomy sites. Clinical outcomes appear to have been assessed only at the time of radiographic healing and did not show any differences between groups at that time point. The literature on pulsed US for distraction osteogenesis (small trials) has shown inconsistent results. The evidence is insufficient to determine the effects of the technology on health outcomes.

References

Policy History
Original Effective Date: 05/01/1995
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10/18/2001 Medical Policy Committee review. Policy revised to include ultrasound accelerated healing devices and noninvasive and invasive bone growth stimulators.
11/12/2001 Managed Care Advisory Council approval
06/24/2002 Format revision. No substance change to policy.
01/26/2004 Managed Care Advisory Council approval
03/01/2005 Medical Director review
03/15/2005 Medical Policy Committee review
04/04/2005 Managed Care Advisory Council approval
04/05/2006 Medical Director review
04/19/2006 Medical Policy Committee review. Format revision, including addition of FDA and or other governmental regulatory approval
04/04/2007 Medical Director review
04/18/2007 Medical Policy Committee approval. Coverage eligibility unchanged. Rationale/Source updated
04/02/2008 Medical Director review
04/16/2008 Medical Policy Committee approval. Coverage eligibility unchanged. Removed criterion from patient selection criteria “the fracture gap is 1cm or less.” Rationale/Source updated.
04/02/2009 Medical Director review
04/15/2009 Medical Policy Committee approval. Coverage eligibility unchanged.
04/08/2010 Medical Policy Committee approval
04/21/2010 Medical Policy Implementation Committee approval. Added noninvasive electrical bone stimulation as a treatment of patients with failed lumbar spinal fusion to be eligible for coverage. Added implantable and semi-invasive electrical bone growth stimulators to be investigational. Added semi-invasive electrical stimulation as an adjunct to lumbar fusion surgery and for failed lumbar fusion to
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be investigational. Added invasive, semi-invasive and noninvasive electrical stimulation as an
adjunct to cervical fusion surgery and for failed cervical spine fusion to be investigational. Updated
rationale and references.

04/07/2011 Medical Policy Committee review
10/06/2011 Medical Policy Committee review
10/19/2011 Medical Policy Implementation Committee approval. “Based on review of available data, the
Company may consider low-intensity ultrasound treatment may be considered as a treatment of
delayed union of bones excluding the skull and vertebra to be eligible for coverage” was added to
the coverage statement. Used to be investigational. “Based on available data, the Company
considers implantable and semi-invasive electrical bone growth stimulators to be investigational”
was removed from policy.

06/28/2012 Medical Policy Committee review
07/27/2012 Medical Policy Implementation Committee approval. Criteria for low–intensity ultrasound for fresh
fractures revised.
02/20/2013 Medical Policy Implementation Committee approval. Changed criteria statement for electrical bone
growth stimulation of the spine from “potential” spinal fusion surgery to “lumbar” spinal fusion
surgery for clarification. Deleted the second criteria bullet for the use of electrical bone growth
stimulation of the spine as a treatment for patients with failed spinal fusion, since this is a duplicate
coverage statement in the policy.

06/06/2013 Medical Policy Committee review
06/25/2013 Medical Policy Implementation Committee approval. Replaced “lumbar” with “spinal” in the first
bullet of the criteria for electrical bone growth stimulation of the spine, so that all spinal fusions are
covered with criteria. Deleted “lumbar” from the non-invasive electrical bone growth stimulation
coverage statement for failed spinal fusions. Deleted the investigational statement regarding
cervical fusions.

09/05/2013 Medical Policy Committee review
09/18/2013 Medical Policy Implementation Committee approval. “Based on review of available data, the
Company considers implantable and semi-invasive electrical bone growth stimulators for
use on the appendicular skeleton to be investigational” was added to the coverage
statement.

09/04/2014 Medical Policy Committee review
08/03/2015 Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
09/03/2015 Medical Policy Committee review
03/03/2016 Medical Policy Committee review
03/16/2016 Medical Policy Implementation Committee approval. Reorganized and clarified coverage section.
10/01/2016 Coding update
01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes
03/02/2017 Medical Policy Committee review
03/15/2017 Medical Policy Implementation Committee approval. Immediate postsurgical treatment after
appendicular skeletal surgery, stress fractures, and fresh surgically treated closed fractures added
to existing INV statements. Clarified language in coverage statements. Reduced size of rationale
section and added guidelines section.

Next Scheduled Review Date:  03/2018
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**Coding**

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

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*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. FDA and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
   1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
   2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
   3. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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